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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,643	02/12/2004	Helen Vivian Hsieh	82880	1755

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David W. Highet, VP & Chief IP Counsel
Becton, Dickinson and Company
(Morgan, Lewis & Bockius, LLP)
1 Becton Drive, MC 110
Franklin Lakes, NJ 07417-1880

EXAMINER	
DESAI, ANAND U	
ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
02/18/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/776,643	HSIEH ET AL.	
	Examiner	Art Unit	
	ANAND U. DESAI	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-83* is/are pending in the application.

4a) Of the above claim(s) *43-56,58-77 and 80-83* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57,78 and 79* is/are rejected.

7)☒ Claim(s) *43-56,58-77 and 80-83* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to the amendment filed on November 18, 2008. Claims 43-56, 58-77, and 80-83 have been withdrawn previously.

2. Claims 57, 78, and 79 are currently pending and are under examination.

Oath/Declaration

3. A new oath or declaration is required because inventor Terry Amiss has not dated the oath. The oath has not been executed properly. The wording of an oath or declaration cannot be amended. If the wording is not correct or if all of the required affirmations have not been made or if it has not been properly subscribed to, a new oath or declaration is required.

Response to Remarks

4. Applicant's state the Office will no longer require a newly executed oath or declaration based on an oath or declaration being stale, citing MPEP §602.05. Applicant's arguments filed November 18, 2008 have been fully considered but they are not persuasive. An executed oath is a requirement of the statute 35 U.S.C. 115. In addition, the instant application is a continuation-in-part of U.S.S.N 10/040,077. 37 CFR 1.63 (e) states a newly executed oath or declaration must be filed in any continuation-in-part application, which application may name all, more, or fewer than all of the inventors named in the prior application.

Withdrawal of Rejections

5. The rejection of claims 57, 78, and 79 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn based on the reference to a *E. coli* Glucose/Galactose Binding Protein.

Pending Objections and Rejections

Specification

6. The disclosure is objected to because of the following informalities:

7. The attempt to incorporate subject matter into this application by reference to Galactose/Glucose Binding Protein Accession Number 230520 is ineffective because 37 CFR 1.57 (c) states "Essential material" may be incorporated by reference, but only by way of an incorporation by reference to a U.S. patent or U.S. patent application publication.

8. The incorporation by reference will not be effective until correction is made to comply with 37 CFR 1.57(b), (c), or (d). If the incorporated material is relied upon to meet any outstanding objection, rejection, or other requirement imposed by the Office, the correction must be made within any time period set by the Office for responding to the objection, rejection, or other requirement for the incorporation to be effective. Compliance will not be held in abeyance with respect to responding to the objection, rejection, or other requirement for the incorporation to be effective. In no case may the correction be made later than the close of prosecution as defined in 37 CFR 1.114(b), or abandonment of the application, whichever occurs earlier. Any correction inserting material by amendment that was previously incorporated by reference must be accompanied by a statement that the material being inserted is the material incorporated by reference and the amendment contains no new matter. 37 CFR 1.57(f).

Suggest amending the specification to include the essential material and providing a copy of the incorporated materials per 37 CFR 1.57(e) using a sequence listing. Applicant should also comply with the sequence requirements 37 CFR 1.821-1.825.

Appropriate correction is required.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claim 57 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 6,855,556 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are of overlapping scope. The claims of the issued U.S. Patent are drawn to a composition comprising at least one mutated glucose/galactose binding protein and at least one reporter group attached to said binding protein, wherein said at least one mutated glucose/galactose binding protein comprises at least two amino acid substitutions, said at least two amino acid substitutions recited by a Markush group that includes a cysteine at position 112 and a serine at position 238 (see claim 8). The pending claims encompass a mutated E. coli glucose/galactose binding protein having at least two amino acids substitutions including the substitutions of a cysteine at position 112 and a serine at position 238.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 57, 78, and 79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are rejected under 35 U.S.C. 112, 1st paragraph, Written Description, because the disclosure does not convey the unambiguous sequence of a mutated *E. coli* glucose/galactose binding protein.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, Paragraph 1, "Written Description" Requirement, published at Federal Register, Vol. 66, No. 4, pp. 1099-1111 outline the method of analysis of claims to determine whether adequate written description is present. The first step is to determine what the claim as a whole covers, i.e., discussion of the full scope of the claim. Second, the application should be fully reviewed to understand how applicant provides support for the claimed invention including each element and/or step, i.e., compare the scope of the claim with the scope of the description. Third, determine whether the applicant was in possession of the claimed invention as a whole at the time of filing. This should include the following considerations: (1) actual reduction to practice,

(2) disclosure of drawings or structural chemical formulas, (3) sufficient relevant identifying characteristics such as complete structure, partial structure, physical and/or chemical properties and functional characteristics when coupled with a known or disclosed correlation between function and structure, (4) method of making the claimed invention, (5) level of skill and knowledge in the art and (6) predictability of the art. For each claim drawn to a single embodiment or species, each of these factors is to be considered with regard to that embodiment or species. For each claim drawn to a genus, each of these factors is to be considered to determine whether there is disclosure of a representative number of species that would lead one skilled in the art to conclude that applicant was in possession of the claimed invention. Where skill and knowledge in the art is high adequate written description would require fewer species to be disclosed than in an art where little is known; further, more species would need to be disclosed to provide adequate written description for a highly variable genus.

First, what do the claims as a whole cover? The claims are drawn to a mutated E. coli glucose/galactose binding protein having at least two amino acid substitions selected from a Markush group of substitutions. The claims as currently written are not limited to any particular mutated *E. coli* glucose/galactose binding protein, because no SEQ ID NOs: are provided for the binding proteins. The claims encompass a genus of any mutated *E. coli* glucose/galactose binding protein.

Second, how does the scope of the claims compare to the scope of the disclosure? The disclosure describes the galactose/glucose binding protein by reference to an accession number, although the claims refer to a genus of mutant glucose/galactose binding proteins, which is a

composition with a mutated *E. coli* glucose/galactose binding protein, not "the" glucose/galactose binding protein that is mutated.

Third, the factors need to be considered.

(1) What was actually reduced to practice?

The *E. coli* galactose/glucose binding protein identified by accession number is shown to be mutated with reporter groups to correlate varying glucose/galactose concentrations.

(2) Is there disclosure of drawings or structural chemical formulas?

There is reference to the *E. coli* galactose/glucose binding protein in paragraph [0025].

(3) Are there sufficient relevant identifying characteristics disclosed?

There is insufficient identifying characteristics disclosed for any mutated glucose/galactose binding protein, because the sequence structure is not disclosed for the parent unmodified amino acid primary structure.

(4) Is there at least one method of making the claimed invention disclosed?

The use of the *E. coli* galactose/glucose binding protein as the parent compound to be mutated is disclosed. The specification discloses the modification of a single species of *E. coli* mutated glucose/galactose binding protein conjugated with two luminescent reporter groups to correlate varying glucose/galactose concentrations.

(5) What is the level of skill in the art and what knowledge is present in the art?

/ (6) What is the level of predictability of the art?

The prior art has shown a large quantity of experimentation is often necessary to overcome the unpredictable nature of protein modifications. Marvin and Hellinga (IDS 2/18/2005; document page 3; previously cited) disclose the unpredictability of using any

fluorophore as a conjugate by disclosing that acrylodan and IANBD are sensitive to changes in the polarity of their microenvironment (see page 10, section titled Microenvironment of the Fluorophore Conjugates). Applicants own disclosure describes the state of the art, which discloses specific mutations of sites and/or attachment of certain reporter groups may act to modify a binding constant in an unpredictable way. Applicants also state that it is currently not possible to predict the effect on either the binding constant or the selectivity based on the position of any reporter group, or amino acid substitution in the protein (see paragraph [0009] of instant disclosure).

Consequently, there would be a high level of skill necessary to determine what conditions are required to disclose to the public a genus of mutated glucose/galactose binding proteins with two reporter luminescent groups that still retain the implied function of measuring the variation in glucose and/or galactose concentration that is correlated to the luminescent signal generated. Therefore, there is a high level of unpredictability in the art.

Thus, having analyzed the claims with regard to the Written Description guidelines, it is clear that the specification does not disclose a representative number of *E. coli* glucose/galactose binding protein species which would lead one skilled in the art to conclude that applicant was in possession of the claimed invention.

Claims 78 and 79 are rejected for depending on claim 57 and failing to cure the deficiencies.

Claim Objections

13. Claims 43-56, 58-77, and 80-83 are objected to because of the following informalities:

14. The status identifiers for the claims are not identified as (Withdrawn).

Appropriate correction is required.

Conclusion

15. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI whose telephone number is (571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

February 14, 2009
/ANAND U DESAI/
Primary Examiner, Art Unit 1656